

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N-0195]

DMB

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Certifier	<i>A. Adams</i>

Guidance for Industry: Fish and Fishery Products Hazards and Controls Guidance, Third Edition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance for industry (third edition) entitled "Fish and Fishery Products Hazards and Controls Guidance" (the guidance). The guidance supports and complements FDA regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point (HACCP) methods. The guidance represents the agency's current views on potential hazards in seafood products and how to control them, and it is designed to assist seafood processors in the development of HACCP plans. The guidance is revised about every 2 years to address comments and to reflect our current understanding of seafood hazards and control methods.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the guidance to the Office of Seafood (HFS-415), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington DC 20204. Send one-self adhesive address label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Anthony P. Brunetti, Center for Food Safety and Applied Nutrition (HFS-415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3150.

SUPPLEMENTARY INFORMATION:

I. Background

We (FDA) are announcing the availability of the third edition of the “Fish and Fishery Products Hazards and Controls Guidance” (the guidance). A summary of the changes incorporated in the third edition are listed in the introduction of the guidance.

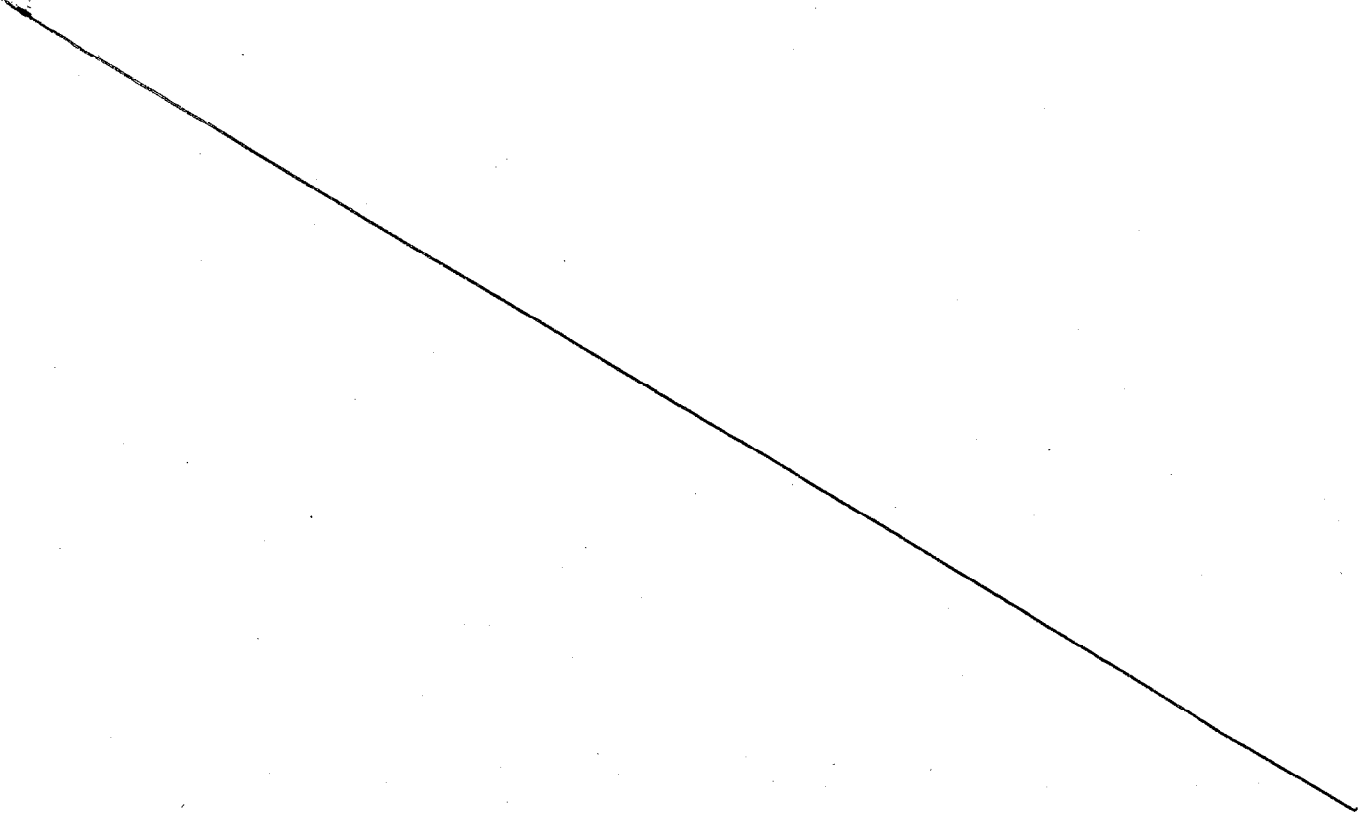
Under our HACCP regulations at parts 123 and 1240 (21 CFR parts 123 and 1240) processors and importers of fish and fishery products are required to operate preventive control systems that incorporate the principles of HACCP. Under § 123.6(g), fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) if a processor or importer fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the guidance is to help processors and importers of seafood products identify the likelihood that a food safety hazard may occur in their product, and to guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur.

We published the first edition of the guidance in September 1996, about 1 year before the seafood HACCP regulations became effective, and issued the second edition in January 1998. The guidance describes current information relating to: (1) Potential hazards associated with the known commercial species of vertebrate and invertebrate seafood; (2) potential hazards associated with certain processing operations; (3) HACCP strategies that may be used to control the potential hazards; and (4) other information related to food safety.

FDA is not seeking public comment before implementing this edition of the guidance because we have determined that it is not feasible or appropriate in accordance with 21 CFR 10.115(g)(2). We revise this guidance relatively frequently to keep it up-to-date. When revising each edition,

we consider both any formal comments received on the previous edition and informal feedback obtained from our HACCP inspections. Thus, each edition is effectively a “draft” for the next edition and each new addition has the benefit of significant up-to-date public comment.

The guidance represents the agency’s current thinking on the potential hazards that are associated with various seafood species and certain processing operations, and how their occurrence can be avoided with HACCP controls when they are reasonably likely to occur, as required under parts 123 and 1240 (pertaining to the safe and sanitary processing of fish and fishery products). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

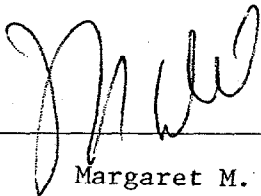


II. Electronic Access

Copies of this guidance for industry are available on the Internet at <http://vm.cfsan.fda.gov/~dms/guidance.html>.

Dated: 8/20/01

August 20, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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